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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/605,086	09/08/2003	Muhammed Majeed		2085

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EXAMINER	
DRODGE, JOSEPH W	
ART UNIT	**PAPER NUMBER**
1723	

DATE MAILED: 12/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/605,086	MAJEED ET AL.	
	Examiner	Art Unit	
	Joseph W. Drodge	1723	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are replete with terminology introducing indefiniteness and vagueness including phrases starting with "such as" (claims 1-3 and 11), is useful (claims 12-14), but not limited to (claim 2), "may be" (claim 7) etc.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,3-9,11 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Saettone et al patent 6,346,273.

Saettone et al disclose solubilizing of diterpenes at least including forskalin by adding complexing agent that may be cyclodextrin [claim 3], and dissolving into a water solution (column 5, lines 10-33 and 60-66 and column 8, lines 10-15). For claim 4, see instant claim 3 drawn to solution material percentages. For claims 5 and 6, see crystallizing of a suspension in column 2, lines 65-66, and agitation and filtration (column 3, lines 11-21 and column 6, lines 35-42). For claims 6-8, forming of eyedrops for treatment of glaucoma and other ophthalmic conditions is at column 2, line 43; column 1, line 32 and column 8, lines 65-67. For claim 9, addition of PVP is extensively discussed starting at column 5, line 60, while use of "eyedrops" would inherently treat "dry eye". For claim

11, topical administrations are found at column 1, lines 44-46. For claim 13, formation of waters soluble formulations are at column 2, line 53.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2,12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saettone et al in view of Majeed et al patent 5,804,596.

Claim 2 differs in requiring the active substance being derived from the coleus plant. Majeed et al teach extraction of forskalin from the coleus plant at column 2, lines 55-61. It would have been obvious to one of ordinary skill in the art to have utilized the coleus plant as a starting material for the prepartions of Saettone et al, as taught by Majeed, so as to utilize a relatively pure form of starting material having standardized amounts of active material.

Claims 12 and 14 differ in requiring use of the medication to treat obesity or promote lean body mass. Majeed et al also teach forskalin being useful in such treatments at column 12, lines 19-35. It would have been obvious to one of ordinary skill in the art to have utilized the forskalin of Saettone et al to treat obesity and enhance lean body mass, as taught by Majeed et al, since forskalin has the property of enhancing lipolysis of fat cells in vitro.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Saettone et al in view of Spence et al patent 6,540,895.

Claim 10 differs in the end use of the forskalin as a molecular probe material, such is taught by Spence et al at column 22, lines 49-67.. It would have been obvious to one of ordinary skill in the art to have utilized the manufactured forskalin of Saettone et al as a molecular probe material, as taught by Spence et al, since forskalin has the property of reflecting or adsorbing fluorescence, hence for enhancing analysis of cellular environments.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Bonte et al patent 6,471,972 is of interest with respect to forskalin

as a cosmetic or anti-wrinkle product. Conway et al patent 5,846,992 and Sears et al patent 4,476,140 are directed to ophthalmic solutions and treatment of glaucoma and eye reddening. Preparation of forskalin is found in Tattee et al patent 5,302,730 and patent 5,070,209.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Drodge at telephone number 571-272-1140. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can reached at 571-272-1151. The fax phone number for the examining group where this application is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either private PAIR or Public PAIR, and through Private PAIR only for unpublished applications. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JWD

December 7, 2004

Joseph Drodge

JOSEPH DRODGE
PRIMARY EXAMINER